

**Remarks**

Claims 1-10, 12-21, 24, 27, 32, 34-36, and 38-42 are pending upon entry of the foregoing amendments.

**Amendments to the Claims**

Claims 1, 12, and 34 has been amended to more clearly define the device structure and operation and to more precisely describe the cooperation among the elements or steps of the claims, in order for the Examiner to more readily understand how Applicants' claims are patentably distinct from the cited prior art.

Claims 1, 12, and 34 have been amended to specify that each reservoir cap is *in register with an opening* of one of the reservoirs (claims 1 and 12) or covers a *discrete predefined* opening in each reservoir (claim 34). Claims 1 and 12 also have been amended to make explicit that the reservoir cap *prevents the parathyroid hormone from being released* from the medical device. Support for these amendments is found at least in Figure 2A and at page 18, lines 11-15.

Claim 1 also has been amended to make explicit that the step of electrothermal ablation of the reservoir cap, to disintegrate it, requires passing an electric current *through* the reservoir cap. Support for the amendment is found at least at page 15, lines 16-20, of the original specification.

New claims 41 and 42 have been added. Support for these claims can be found, for example, at page 15, lines 3-14.

**Rejections Under 35 U.S.C. § 103**

Claims 1, 12, 17-20, 24, 27, 32, 34-36, and 38-40 were rejected under 35 U.S.C. § 103(a) as obvious over U.S. Patent 6,349,232 to Gordon (hereinafter “Gordon”) in view of U.S. Patent 5,660,846 to Cheikh (herein after “Cheikh”). Claims 2-10 and 13-16 where rejected under 35 U.S.C. § 103(a) as obvious over Gordon and Cheikh, in further view of Rubin et al., “The Potential of Parathyroid Hormone as a Therapy for Osteoporosis,” *Int. J. Fertil.* 47(3):103-15 (2002) (hereinafter “Rubin”). Claim 21 was rejected under 35 U.S.C. § 103(a) as obvious over Gordon and Cheikh, in further view of U.S. Patent No. 6,011,011 to Hageman (hereinafter “Hageman”). The rejections are respectfully traversed.

Applicants submit that the rejections are erroneous for the reasons set forth in Applicants’ Amendment and Response to Office Action filed September 24, 2007. In addition, Applicants respectfully submit that the Examiner’s reasons for sustaining the rejections in the Office Action mailed October 29, 2007, are not based on a proper reading of Applicants’ claims or on an accurate reading of Gordon, as detailed below. Applicants nevertheless have amended the claims to further negate the interpretations taken by the Examiner.

At page 4 of the Office Action, the Examiner alleges that “the features upon which applicant relies (i.e., the reservoir cap must be both a barrier and resistive heating element) are not recited in the rejected claims.” Applicants disagree. Claims 1 and 12 specify that the reservoir cap *separates* the release system from an environment outside of the reservoirs, and claim 34 specifies that the reservoir cap *covers a discrete opening* in the reservoir. The claims undeniably indicate that no exposure or release can occur until the reservoir cap has been disintegrated. Accordingly, one of ordinary skill in the art would read the claims to require that

the reservoir cap acts as a barrier between the inside and the outside of the reservoir. Furthermore, all claims explicitly recite that the reservoir cap disintegration occurs “by electrothermal ablation,” which term inarguably *requires* that the reservoir cap also function as a resistive heater (upon initiating passage of electrical current therethrough and until disintegration occurs).

Contrary to the Examiner’s assertion, Applicants are not reading a limitation from the specification into the claims. Rather, Applicants’ are pointing out that the term “electrothermal ablation—which already is part of the claim—has a meaning that Applicants have defined in their specification. For instance, the term is explained at page 15, lines 16-20:

When an effective amount of an **electrical current is applied through the leads and reservoir cap**, the temperature of the reservoir cap is locally increased due to resistive heating, and **the heat generated within the reservoir cap** increases the temperature sufficiently to **cause the reservoir cap to be electrothermally ablated** (i.e., ruptured).

In addition, claim 1 has been amended to explicitly recite the step of “passing an electric current through one or more of the discrete reservoir caps” of the device.

In sum, Gordon does not disclose electrothermal ablation of a discrete reservoir cap or any structure that is in register with, or covering, a reservoir opening, as required by Applicants’ claims. This argument of Applicants distinguishes the prior art from features *recited in the claims*. The Examiner has no reasonable or proper basis to allege otherwise.

The Examiner also asserts that “the walls of the reservoirs are illustrated as distinct from each other in Figs 9 and 10.” Figures 9 and 10 of Gordon admittedly appear to show multiple individual cell enclosures 270. These figures do not, however, indicate discrete *reservoir caps*.

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Cell enclosure 270 is not a reservoir cap. It cannot reasonably be construed to be *both* a substrate and discrete reservoir cap in register with, or covering, a predefined opening of a reservoir.

Moreover, there is no teaching in Gordon that cell enclosure 270 comprises a metal film, as required by Applicants' claim 12. In sum, Figures 9 and 10 fail to show an identical or equivalent structure to that recited in Applicants' claims.

The Examiner also alleges, at p. 4 of the Office Action, that "discrete caps (289) are shown in Fig 12A which are ruptured by 'electrical communication with a heating element.'" This mischaracterizes Gordon and still does not support the rejection.

Gordon teaches that 289 is a "rupturable **opening**"; it does not describe 289 as a "reservoir cap." Because an "opening" is the *absence* of material and not a positive structure, one of ordinary skill in the art would understand rupturable opening 289 as illustrated in Fig. 12A and described at Col. 9, Ln. 50 to Col. 10, Ln. 23 to be a region of coversheet 290 that is intended to rupture. Rupturable opening 289 and coversheet 290 are not separate structures or materials. The rupturable opening region of the coversheet is disclosed to be "in electrical communication with a heating element, as described hereinabove with reference to FIGS. 9-11D." However, FIGS. 9-11D do not show a discrete reservoir cap, let alone teach rupture of a discrete reservoir cap by passing an electrical current precisely through a discrete reservoir cap closing off a predefined opening.

Furthermore, rupturable openings 289 cannot simultaneously meet the "reservoir cap" element of Applicants' claims *and* still need a *separate* "heating element" in communication with it to cause the rupturable opening to open. With Applicants' claimed devices in which the

reservoir cap disintegrates by electrothermal ablation, the discrete reservoir cap *is* the heating element; Applicants' device need not include a separate one.

At page 4 of the Office Action, the Examiner also states that "the walls at the top or exposed side of the device must be ruptured for the device to deliver the medication" and then the Examiner somehow leaps to the conclusion that "therefore the top walls of the reservoirs (shown as discrete in Figs. 9-10) are considered discrete reservoir caps." Applicants submit that the conclusion does not follow from the premise. Whether a structure becomes ruptured in Gordon to permit release does not by any reasonable measure mean that that structure is identical or equivalent to Applicants' reservoir cap. First, "the walls at the top or exposed side of the device" are not *discrete* caps. Second, they are not *in register with an predefined opening*. Third, the walls the Examiner refers to are far more akin to Applicants' "substrate" element in which the reservoirs are defined, rather than the "discrete reservoir cap" through which an electric current is passed in Applicants' claims. In sum, the Examiner's conclusion is neither a fair interpretation of Gordon nor based on a reasonable interpretation of the elements defining Applicants' claims.

The Examiner also improperly construes the "means for disintegrating one or more discrete reservoir caps by electrothermal ablation" in Applicants' claim 12. The Examiner alleges, at page 4 of the Office Action, that the resistor 272 disclosed in Gordon meets this limitation. It cannot. Gordon's resistor 272, even when coupled to a power source, is not a structure capable of disintegrating one or more discrete reservoir caps *by electrothermal ablation*. A resistor 272 suitable for heating an *adjacent* cell enclosure 270 is neither identical nor

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equivalent to Applicants' means in which an input lead and an output lead deliver electric current *directly* through a discrete reservoir cap. In contrast to Applicants' claimed devices and methods, Gordon uses a resistance heating element that is a *distinct* structure from the cell enclosure. Gordon teaches that heat must flow *from* heating element 272 *to* the cell enclosure 270. In contrast, Applicants' claimed methods and devices require a discrete, electrically conductive reservoir cap that *itself* is heated by *internally generated heat* caused by passage of an electrical current therethrough. The heating is localized within the reservoir cap. The internal heating is sufficient to disintegrate (ablate) the reservoir cap itself, thereby exposing the reservoir opening over which the reservoir cap previously existed. This is entirely different from Gordon's teaching of the use of a *separate* heating element; Gordon does not teach that a discrete reservoir cap *itself* can serve as the heating element.

The Office Action also fails to provide any explanation for the rejection of claims 38-40, which is contrary to the mandate under 37 C.F.R. § 1.104(c)(2) that the pertinence of each reference to each claim be clearly explained, where, as here, it is not apparent. The Examiner has not explained how Gordon is alleged to disclose the features recited in claims 38, 39, or 40. Gordon gives absolute no guidance about materials of construction or dimensions of an input lead, output lead, or reservoir cap, for one of ordinary skill in the art to design an implantable device in which electric current flowing through a reservoir cap via physically and electrically connected input and output leads yields "an increase in electrical current density in the reservoir cap relative to the current density in the input and output leads" (Claim 38 or Claim 40) or in which the material forming the reservoir cap has a different electrical resistivity, thermal

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diffusivity, and/or lower melting temperature than the material forming the input and output leads (Claim 39 or Claim 40).

Assuming one of ordinary skill in the art at the time of Applicants' invention would have had a reason (which it is respectfully submitted, the artisan of ordinary skill would not) to combine Gordon with Cheikh, Rubin, and/or Hageman, the combination of references nevertheless would fails to disclose or suggest a device that includes structures or methods for electrothermal ablation of a discrete reservoir cap to initiate release of PTH, as required by Applicants' claims. Cheikh, Rubin, and Hageman do not supplement the deficiencies of Gordon.

### **Conclusions**

Allowance of each of the pending claims 1-10, 12-21, 24, 27, 28, 32, 34-36, and 38-42 is therefore respectfully solicited.

Respectfully submitted,

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